

REMARKS

i. Status of the claims and application

Claims 26-54 are pending. Claims 1-25 have been cancelled herein without prejudice or disclaimer and solely for the purpose of expediting prosecution. Applicants have taken this opportunity to rewrite the originally-filed claim set for grammatical purposes and to improve the clarity of various methodological steps. For this reason, Applicants have added new claims 26-54 to concisely capture their invention, but no new matter has been added. Indeed, all of the newly added claims find support in the originally filed specification and in original claims 1-25.

Applicants believe, therefore, that the new concise set of claims imposes no new search burden on the Examiner, and that the claims are no longer “unduly narrative.” For at least these reasons, Applicants respectfully request that the Examiner enter claims 26-54.

Applicants thank the Examiner for suggesting that they make a biological deposit pursuant to the Budapest Treaty protocol to evidence enablement of Applicants’ pRT99GUS plasmid. Since new independent claim 26 does not recite that plasmid, however, Applicants do not believe it is necessary to pursue this course of action.

The rejection of claims 1-25 under 35 U.S.C. § 112, second paragraph for alleged indefiniteness, is now moot, because claims 1-25 are now canceled. Applicants assert that new claims 26-54 are clear, unambiguous, and comport with antecedent basis requirements.

***ii. The presently claimed invention is enabled,
as evidenced by Applicants’ experiments***

The Examiner rejected claims 1-25 under 35 U.S.C. § 112, first paragraph, as allegedly failing to comply with the enablement requirement. At the outset, Applicants contend that this rejection is moot because they have canceled the rejected claims. The cancellation of the claims is no indication that Applicants acquiesce with the Examiner’s rationale for rejecting the claims. Applicants canceled claims 1-25 solely for the purpose of expediting prosecution. Nevertheless, Applicants take this opportunity to address and rebut the various grounds of non-enablement against the originally-filed claims.

The Examiner alleges non-enablement because the claimed invention covers “all tea (*Camellia sinensis*), and all explants.” Office Action at page 8. She states that “Applicant merely provides prophetic examples of a method of biolistics transformation of *Camellia sinensis* derived from various explants” (Office Action at page 8); and alleges that Applicants have “not provided even a single working example of a biolistic transformation of *Camellia sinensis* using any specific explant” (Office Action at page 9).

(a) *Contrary to the Examiner’s allegations, the present specification relates four experimental examples.*

Contrary to the Examiner’s allegations, the present specification relates four experimental examples. Applicants draw the Examiner’s attention to panels (d) to (r) of Figure 1 of the present application, which are photographs of tea leaf explants that have been biolistically transformed according to the methods and conditions detailed in experimental examples 1, 2, 3, and 4.

Example 1 at page 13 of the specification explains in particular detail how the inventors manipulated the leaf explants and PDS-1000/He particle delivery system so as to transform the plant material. Applicants relate in the example how they prepared the suspension of gold particles; the size of gold particles that they used; the various concentrations of plasmid DNA that they incorporated into the “gold suspension”; the conditions that they used in the helium-powered delivery system; and the subsequent GUS assays and culturing techniques that they relied on to identify successfully-transformed explants and to grow shoots from them. Figure 1 shows the results of these actual experiments.

Applicants also tested different concentrations of osmotic agents (Example 2, page 14); explants different cultivars (Example 3, page 14); and different explants, such as somatic embryos, zygotic embryos, and embryogenic calli (Example 4, page 14).

The specification of a patent application need not contain *any* examples, working or prophetic, to establish enablement of a claimed invention. *In re Borkowski*, 422 F.2d 904, 908 (CCPA 1970). The present specification need only disclose the invention in such manner that one skilled in the art may practice it without undue experimentation. Given the amount

of guidance and demonstrative evidence that Applicants have provided, the present specification meets that enablement requirement. Indeed, Section 2164.02 of the MPEP makes clear that “a single working example in the specification for a claimed invention is enough to preclude a rejection which states that nothing is enabled since at least that embodiment would be enabled.”

(b) *There is no undue experimentation required to practice the presently claimed invention*

The present specification clearly discloses the claimed invention as covering a method for producing a transgenic tea plant that has been cultured from an explant exposed to biolistic DNA transformation, and how to improve the likelihood of successful transformation of an explant using particle penetration. Hence, the specification teaches what biolistic system parameters may be modified so as to obtain a “high frequency” of transformation, while increasing the efficiency of explant regeneration with minimal plant cell damage. See “Objects of the Invention” at page 3 of the specification.

Accordingly, Applicants have taught that various species of explants and cultivars of *Camellia sinensis* can be subjected to biolistic transformation and how to enhance the frequency of transformation of a particular explant. It is well established that “determining operable embodiments requires only routine screening, which does not amount to ‘undue’ experimentation. See *Ex parte Mark*, 12 USPQ2d 1904, 1906-07 (BPAI 1989).

Hence, Applicants believe that the specification is fully commensurate with the scope of the present claims and that the skilled artisan would not have to perform undue experimentation to practice the claimed invention.

As mentioned above, Applicants consider the rejection under paragraph 1 of 35 U.S.C. § 112 to be moot, since they have canceled claims 1-25. Nevertheless, they kindly ask the Examiner to take their comments in support of enablement into consideration when examining new claims 26-54.

iii. Conclusion

Applicants believe that the present application is now in condition for allowance. Favorable reconsideration of the application as amended is respectfully requested. The Examiner is invited to contact the undersigned by telephone if it is felt that a telephone interview would advance the prosecution of the present application.

The Commissioner is hereby authorized to charge any additional fees which may be required regarding this application under 37 C.F.R. §§ 1.16-1.17, or credit any overpayment, to Deposit Account No. 19-0741. Should no proper payment be enclosed herewith, as by a check being in the wrong amount, unsigned, post-dated, otherwise improper or informal or even entirely missing, the Commissioner is authorized to charge the unpaid amount to Deposit Account No. 19-0741. If any extensions of time are needed for timely acceptance of papers submitted herewith, Applicant hereby petitions for such extension under 37 C.F.R. §1.136 and authorizes payment of any such extensions fees to Deposit Account No. 19-0741.

Respectfully submitted,

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